

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

CIVIL ACTION  
NO: 09-10040

DR. BERISH RUBIN and  
DR. SYLVIA L. ANDERSON,  
Plaintiffs,

vs.

THE GENERAL HOSPITAL CORPORATION,  
Defendant.

COMPLAINT

Plaintiffs, Drs. Berish Rubin and Sylvia L. Anderson  
allege as follows:

Nature of the Action

1. This is a civil action pursuant to 35 USC §256 to correct the inventorship of U.S. Patent Nos. 7,388,093 (the "'093 Patent") and 7,407,756 (the '756 Patent"), a true and correct copy of each patent is attached hereto as Exhibit A & B respectively. The '093 Patent is entitled "Gene For Identifying Individuals With Familial Dysautonomia" and is directed to a kit and an oligonucleotide probe for detecting the mutations associated with Familial Dysautonomia ("FD") in humans. The '756 Patent is

entitled "Methods For Detecting Mutations Associated With Familial Dysautonomia" and is directed to methods for assaying a biological sample for the presence of a mutation associated with Familial Dysautonomia in humans.

2. This action is necessary because both of the '093 and '756 patents fail to name as inventors the individuals who conceived the invention claimed therein. Specifically, the '093 and '756 patents name as inventors two individuals who, on information and belief, were not responsible for the conception of the subject matter claimed in each patent. The patents at issue fail to name two individuals (the nominative Plaintiffs) who were responsible for conception of the claimed subject matter and are the true inventors, or at least, co-inventors of the patented inventions.
3. On information and belief, the two individuals named as co-inventors on the '093 and '756 patents assigned their interest in both patents to The General Hospital Corporation ("GHC").
4. On information and belief, GHC was responsible for the preparation and prosecution of the applications

before the United States Patent and Trademark Office ("USPTO") that eventuated as the '093 and '756 patents.

5. Both the '093 and '756 patents have significant commercial potential because knowledge of the mutations associated with FD permit, *inter alia*, the screening for FD carriers.

**Parties**

6. Plaintiff, Dr. Berish Y. Rubin is a principal investigator in the FD field for almost a decade. Dr. Rubin has well-over seventy peer-reviewed publications in numerous scientific journals. Plaintiff, Dr. Sylvia L. Anderson is similarly a principal investigator in the FD field. Dr. Rubin resides in New York and Dr. Anderson resides in New Jersey.
7. Defendant, The General Hospital Corporation is located in, and incorporated under the laws of the Commonwealth of Massachusetts. The GHC is the record assignee of the '093 and '756 patents.

**Jurisdiction and Venue**

8. This action arises under the Patent Laws of the United States, 35 U.S.C §1 *et seq.* Accordingly, this Court has jurisdiction over the subject matter of the action pursuant to 28 U.S.C. §§1331 and 1338(a), and 35 U.S.C §256.
9. Venue is proper in this District under 28 U.S.C. §1391(a) and (c) because the GHC can be found in this District. Specifically, the GHC has its principal place of business in this District.

**Statement of Facts**

10. The invention claimed in the '093 patent is directed to a kit and an oligonucleotide probe for detecting the mutations associated with Familial Dysautonomia ("FD") in humans. The invention claimed in the '756 patent is directed to methods for assaying a biological sample for the presence of mutations associated with Familial Dysautonomia in humans.
11. Prior to January 2001, Rubin and Anderson, in collaboration with Dor Yeshorim (a committee for the prevention of Jewish genetic diseases founded in the early 1980s), began research to identify mutations responsible for FD. They recognized that the

identification of such mutations would enable the identification of carriers of this genetic disorder and could result in the development of effective therapeutic approaches for individuals with FD.

12. Over several months, Drs. Rubin and Anderson performed numerous experiments in an effort to identify the defective FD gene.

13. During 2000, as a result of their experiments, Rubin and Anderson discovered that two mutations in the gene encoding a protein called I<sub>k</sub>B kinase complex-associated protein (IKAP) were responsible for FD. Eager to report this discovery, Rubin and Anderson prepared a scientific article for publication. The article, entitled "Familial Dysautonomia Is Caused By Mutations Of the IKAP Gene" was submitted for publication to the journal American Journal of Human Genetics ("Journal") on December 21, 2000. The article was published by the Journal on January 22, 2001. A true and correct copy of the 2001 article is attached hereto as Exhibit C.

14. Notably, the article describes the precise region of the IKAP gene where the FD mutations are found, an identification of the precise mutations, as well as

the characterization of a major and minor mutation.

In the case of the minor mutation, the authors (Rubin and Anderson) note that the mutation results in defective phosphorylation of IKAP protein.

15. The '093 and '756 patents co-opt and claim what Rubin and Anderson described in the 2001 Article. As elucidated hereinbelow, a summary of critical aspects of the 2001 Article, if not the entire draft article itself, was improperly possessed by at least one of the named inventors on the '093 and '756 patents (Dr. Gusella) without the knowledge or consent of Rubin and Anderson and in fact in direct contravention of their express instruction to the Editor at the Journal that Gusella and his colleagues be sequestered from any peer or prior review of the information set out in the article. For example, the 2001 article discloses a mutation, described as a "thymidine (T) to cytosine (C) transition" at a particular position in the IKAP-encoding gene which results in the generation of an IKAP mRNA which lacks a particular exon. The 2001 article further delineates a second mutation, described as a "G-C transversion of nucleotide 2390 in exon 19 of the

reported IKAP cDNA in the DNA of cells bearing the minor FD haplotype" (i.e. mutation). This mutation is stated to disrupt a phosphorylation site causing reduced phosphorylation of the IKAP protein in cells. (Exhibit C at 754).

16. The original patent application in the chain of applications from which the '093 and '756 patents eventuated was filed in the USPTO on January 6, 2001. That is, between the date of submission of the Article to the Journal and its publication. The original patent application named Susan Slaugenhauspt and James F. Gusella. Drs. Gusella and Slaughenhauspt were known by Drs. Rubin and Anderson to be working in the FD field before submission of the 2001 article to the American Journal of Human Genetics.

17. On December 20, 2000, Dr. Rubin wrote to the Editor of The American Journal of Human Genetics attaching a manuscript (that would become the 2001 Article) for review and publication. In the letter to the Editor, Dr. Rubin identified four individuals who he believed would be qualified to review the manuscript. Dr. Rubin expressly identified those who should not review the article noting:

"As this area of research has been for many years the focus of the laboratories of Drs. Felicia B. Axelrod, Anat Blumenfeld, Xandra O. Breakfield, James F. Gusella, Channa Maayan and Susan Slaughenhaupt, we ask that our manuscript not be sent to these individuals for review." (Exhibit D)

18. On December 21, 2000, the Editor of the Journal confirmed receipt of the manuscript entitled "Familial Dysautonomia is caused by mutations of the IKAP gene." The Editor noted in his acknowledgement "If the manuscript is sent out for external review, we expect to inform you of our decision concerning publication within 4 weeks." (Exhibit E)

19. On December 27, 2000, reflecting a conversation between himself and the Editor of the Journal, wherein the Editor expressed willingness to consider the manuscript for "fast-track" review, Dr. Rubin urged acceptance of the article in 2000, anxious to be the first to publish this important work. (Exhibit F)

20. On information and belief and blatantly contrary to the explicit request and condition imposed by Dr. Rubin in his December 20, 2000 letter, the Journal sent the manuscript, or a summary of its critical aspects, including the descriptions hereinabove

noted, to Dr. James F. Gusella, one of the named individuals on the '093 and '756 patents. (Exhibit G).

21. On information and belief, this occurred prior to January 6, 2001, the date upon which the patents in issue were first filed.

22. On information and belief, Gusella and/or his colleagues had in his/their possession, the manuscript or the summary aforesaid prior to January 6, 2001.

23. On information and belief, Gusella and/or his colleagues read the manuscript or summary aforesaid, understood its import, and incorporated, claimed and derived features described in those materials (then publicly still unknown), in the patent application filed January 6, 2001, all without the knowledge or consent of Rubin or Anderson.

24. The subject matter of Claims 1-10 of the '093 patent was thus in fact conceived in whole or in part by Drs. Rubin and Anderson. Specifically, the specific recognition of the FD1 & FD2 mutations as associated with the claimed kits and probes for detecting FD was

the precise discovery that resulted from the research conducted by Drs. Rubin and Anderson, as reflected in the 2001 Article.

25. The subject matter of Claims 1-8 of the '756 patent was thus in fact conceived in whole or in part by Drs. Rubin and Anderson. Specifically, the specific recognition of the FD1 & FD2 mutations associated with the claimed methods for assaying for the presence of a mutation associate with FD in a human subject was the precise discovery that resulted from the research conducted by Drs. Rubin and Anderson, as reflected in the 2001 Article.

Count I  
Complete Substitution of Inventors  
Pursuant to 35 U.S.C. §256

26. Plaintiffs repeat and reallege the allegations set forth in paragraphs 1-25 of the Complaint as if those allegations have been fully set forth herein.

27. Drs. Rubin and Anderson were the first persons to conceive the subject matter described and claimed in the '093 and '756 patents.

28. Drs. Rubin and Anderson are the true and only co-inventors of the inventions described and claimed in the '093 and '756 patents.

29. Pursuant to 35 U.S.C. §256, Dr. Rubin and Dr. Anderson should be substituted for the two presently named inventors of the '093 and '756 patents.

30. Pursuant to 35 U.S.C. §256, Dr. Rubin and Dr. Anderson should be added to the two presently named inventors of the '093 and '756 patents.

31. The omissions of Drs. Rubin and Anderson as inventors on the '093 and '756 patents occurred without any deceptive intent on their part.

Count II  
Addition of Co-inventors

32. Plaintiffs repeat and reallege the allegations set forth in paragraphs 1-31 of the Complaint as if those allegations have been fully set forth herein.

33. Rubin and Anderson conceived subject matter described and claimed in '093 and '756 patents.

34. Rubin and Anderson are co-inventors of the invention described and claimed in '093 and '756 patents.

Count III  
Invalidity of the '093 and '756 Patents  
Pursuant to 35 U.S.C. §102(f)

35. Plaintiffs repeat and reallege the allegations set forth in paragraphs 1-34 of the Complaint as if those allegations have been fully set forth herein.
36. Drs. Slaugenhaus and Gusella did not themselves invent the subject matter described and claimed in the '093 and '756 patents.
37. Pursuant to 35 U.S.C. §102(f) the Court should invalidate both patents for failure to list the proper inventors.

Prayer for Relief

**WHEREFORE**, Plaintiffs pray that this Court enter judgment:

- (a) Ordering the substitution of Dr. Berish Y. Rubin and Dr. Sylvia L. Anderson for Dr. Susan Slaughenhaus and Dr. James F. Gusella as the true inventors of the '093 and '756 patents;
- (b) Alternatively to (a), naming Rubin and Anderson co-inventors of '093 and '756 patents;
- (c) Alternatively to (a) or (b), invalidating the '093 and '756 patents under 35 U.S.C. §102(f); and
- (d) Awarding such additional and further relieve as the Court may deem just and proper.

THE PLAINTIFFS DEMAND TRIAL BY JURY ON ALL COUNTS TO  
WHICH THEY ARE ENTITLED

Respectfully submitted,  
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